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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,386	07/01/2003	Sudershan K. Arora	RLL-9.2US	1529
26815	7590	10/21/2004	EXAMINER	
RANBAXY INC. 600 COLLEGE ROAD EAST SUITE 2100 PRINCETON, NJ 08540			KHARE, DEVESH	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/611,386

Applicant(s)

ARORA ET AL.

Examiner

Devesh Khare

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/10/2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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Applicant's amendment and response filed on 06/10/2004 is acknowledged. Claims 1-4 and 7-14 have been cancelled. Claim 5 has been amended.

The rejection of claims 5 and 6, under 35 U.S.C. 112, second paragraph, has been overcome through applicants' amendment.

Claims 5 and 6 are currently pending in this application.

**35 U.S.C. 103(a) rejection**

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

**Claims 5 and 6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Arora et al.(Arora) (U.S. Patent #5,637,570) in view of Bouveng (Acta. Chem. Scand. 1961, 15, 96-100) of record.

Claims **5 and 6** are drawn to a process for preparing compounds of Formula I by treating the compound of Formula II with an isocyanate in a solvent. Dependent claim limitations include the substituent R<sub>2</sub> is -NH(CH<sub>2</sub>)<sub>n</sub>-pyrrolidinyl, -piperidinyl, -morpholinyl or -hexamethyleneimino.

Arora teaches a process for the preparation of the 2,3-O-isopropylidene- $\alpha$ -L-xylo-2-hexulofuranose compounds wherein the hydroxyl group at C-4 is substituted with a

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nitrogen containing heterocyclic moiety (abstract). Arora discloses that the said compounds exhibit greater potency for cancer treatment and provides ease of oral administration when the 4-OH is substituted with nitrogen containing heterocyclic moiety (col. 2, lines 49-60). Arora discloses the preparation of 2,3-O-isopropylidene- $\alpha$ -L-xylo-2-hexulofuranose compounds wherein substituent  $R_2$  is  $-\text{NH}(\text{CH}_2)_n$ -pyrrolidinyl, -piperidinyl, -morpholinyl or -hexamethyleneimino (cols. 4-6, scheme 1 and the compounds in cols. 7-8). Arora differs from the complete scope of the applicants invention in that Arora does not disclose the preparation of the 2,3-O-isopropylidene- $\alpha$ -L-xylo-2-hexulofuranose compounds wherein the free hydroxyl group at C-4 is treated with an isocyanate reagent to produce a nitrogen containing heterocyclic moiety such as carbamate.

Bouveng teaches to transform free hydroxyl group of a carbohydrate to phenylcarbamoyl (carbamate) group (e.g. glucuronoxylan) by converting the phenylisocyanate derivatives of carbohydrates, to phenylcarbamoyl groups (see abstract and experimental on page 98).

It would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the process for conversion of the 4-hydroxy group to its corresponding nitrogen containing heterocyclic moiety of Arora in view of the teachings of Bouveng to a process of conversion of a free hydroxyl group to its corresponding carbamate by treating with an isocyanate reagent because Arora discloses that the said compounds exhibit greater potency for cancer treatment and provides ease of oral

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administration when the 4-OH is substituted with a nitrogen containing heterocyclic moiety (col. 2, lines 49-60).

### ***Response to Arguments***

Applicant's arguments traversing the rejection of claims 5 and 6 under 35 U.S.C 103(a) have been fully considered but they are not persuasive.

Applicant argues, "The disclosure of Arora et al. does not appear to disclose, suggest or provide motivation for modification of the molecule of Formula I at any position in the structure, beyond what is mentioned as possible for R, R<sub>1</sub> or R<sub>2</sub>".

It is noted that Arora et al. disclose that the substitution of free hydroxyl group of L-hexose with O-heterocyclic alkyl, heterocyclic alkyl, N-heterocycle, N-heterocyclic alkyl, etc. groups can make the compounds active to combat various diseases including cancer (col. 2, lines 40-45). Furthermore, Arora et al. disclose that the amine salts are preferred for intramuscular injection (col. 9, lines 1-2).

Bouveng teaches to transform free hydroxyl group of a carbohydrate to phenylcarbamoyl (carbamate) group (e.g. glucuronoxylan).

Indeed, the examiner has established a prima facie case of obviousness rendering claims 5 and 6 rejected under 35 U.S.C. 103(a) by addressing sufficiently all of the limitations set forth in a process for preparing the compounds of 2,3-O-isopropylidene- $\alpha$ -L-xyllo-2-hexulofuranosonic acid of Formula I wherein sugar is substituted at 4-OH with a carbamate group, one skilled in the art would have a reasonable expectation for

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success in combining the teachings of Arora et al. and Bouveng references to accomplish the compounds of 2,3-O-isopropylidene- $\alpha$ -L-xylo-2-hexulofuranosonic acid of Formula I (Arora et al.) wherein sugar is substituted with a carbamate group (Bouveng). The motivation is provided by Arora et al., the prior art suggests that the substitution of free hydroxyl group of L-hexose with O-heterocyclic alkyl, heterocyclic alkyl, N-heterocycle, N-heterocyclic alkyl, etc. groups can make the compounds active to combat various diseases including cancer (col. 2, lines 40-45).

**2. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the

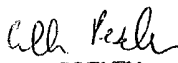
Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.  
Art Unit 1623  
October 10,2004

  
**ELLI PESELEV**  
**PRIMARY EXAMINER**  
**GROUP 1800**